



Dkt. 96700/451

# PEPTIDES FOR THE TREATMENT AND DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS

5 This is a continuation-in-part of co-pending U.S. Application  
No. 08/531,832, filed September 20, 1995, the contents of which are hereby  
incorporated by reference in their entirety. *issued as U.S. Patent No*

<sup>1</sup> issued as U.S. Patent No. 6,001,964,

### Statement of Government Interest

10           This invention was made with government support under NIH Grant Nos. A133184, AR32371, PO1AI33184, and CA39838. As such, the government has certain rights in this invention.

## **Background of the Invention**

15                    Systemic lupus erythematosus (SLE) is a chronic, inflammatory, often  
multisystemic disease which can be acute or insidious in onset. SLE is marked by a  
wide variety of abnormalities, including arthritis and arthralgias, nephritis, central  
nervous system manifestations, pleurisy, pericarditis, leukopenia or thrombocytopenia,  
and hemolytic anemia. One of the most serious complications of SLE is lupus  
20    nephritis. Renal involvement usually occurs early in the course of the illness and is the  
leading cause of death in SLE patients.

Diagnosis of SLE is made on the basis of a number of clinical symptoms such as the so-called "butterfly rash," an erythematous rash which frequently appears on the cheeks of afflicted individuals, crossing the bridge of the nose and becoming more pronounced upon exposure to sunlight; and arthritis which can affect any joint system. However, diagnosis is difficult to verify without appropriate laboratory tests. In this regard, antibodies directed to double-stranded DNA (dsDNA) are diagnostic of SLE and serum titers correlate with disease activity in both humans and mice (Pearson et al., *J. Immunol.* 126:16 (1981)).

30 Although the role of DNA as the significant target antigen of the so called "anti-dsDNA antibodies" which are diagnostic of SLE, is controversial, it is